

Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 1. This sheet, which includes Fig. 1, replaces the original sheet including Fig. 1.

Attachment: Replacement Sheet
Annotated Sheet Showing Changes

REMARKS/ARGUMENTS

Claim 1 and 5-9 are pending. Claim 1, FIG. 1 and the Detailed Description for FIG. 1 have been amended. No new matter has been added with this amendment. Support for the amendment can be found throughout the specification and specifically at page 4 line 21 to page 8 line 10 and FIG. 1. Reconsideration of this Application and entry of this Amendment is respectfully requested.

Drawing Objections

Figure 1 was objected to because reference characters 10 and 20 have been used to designate the sleeve and for not having a reference number for the o-ring. Figure 1 has been amended to correctly indicate the respective structures for reference number 10 and 20 as well as adding a reference number "62" for indicating the o-ring. Figure 1 has also been amended to include reference number "64" in keeping with the amendment to the specification made in response to the §112 rejection, below. The withdrawal of the objection to the drawings is requested.

35 U.S.C. §112 Rejections

Claims 1, 5-9 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Applicant's Detailed Description and accompanying figures have been amended to describe FIG. 1. More specifically, the amendment describes the o-ring location as illustrated in FIG. 1 of the originally filed application at the distal end of the port. The originally filed drawings indicated the position of the oring by showing a groove for the o-ring and a subsequent amendment to FIG. 1 included the o-ring in this groove. For these reasons, the rejection of claims 1, 5-9 under §112, first paragraph is requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant this §102 rejection, the reference cited by the Examiner must show each and every limitation of the claims in complete detail.

A. Claims 1, 5, 7 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,270,521 to Fischell et al., (the Fischell patent).

The Applicant traverses this rejection. The Applicant respectfully asserts that the Fischell patent fails to include each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(b). *See* MPEP 2131. The Applicant asserts that the Fischell patent fails to disclose, teach, or suggest A system for treating a vascular condition comprising a catheter; a stent deployment assembly coupled to the catheter; the stent assembly comprising a coated stent including a stent framework and a drug coating disposed on at least a portion of the stent framework; a protective sleeve removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter at a distal end of the sleeve and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly, and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open, and a port to a vessel, the port including an o-ring having an o-ring inner diameter, the o-ring disposed at a distal end of the port wherein a proximal portion of the sleeve is positioned proximal to the o-ring and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, wherein the o-ring inner diameter is greater than the diameter of the stent deployment assembly and less than the diameter of the distal end of the sleeve, wherein the protective sleeve is sized to be removed from covering the stent framework upon contact of the distal end of the protective sleeve with a proximal side of the o-ring as the stent enters the vessel, as recited in claim 1.

The Examiner continues to allege that Fischell teaches a system for treating a vascular condition comprising “a port to a vessel (18), the port including an o-ring having an o-ring inner diameter (portion of 18 acts as an o-ring), wherein a proximal portion of the sleeve (34) is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter (Fig. 2c)” (see, page 5 of the current Office Action). Further, in Response to Arguments the Examiner alleges that “a portion of element 18 of Fischell, a balloon, acts as an o-ring (the proximal end is a port, the distal end an o-ring)” (see page 7 of the current Office Action).

FIG. 2C of the Fischell patent illustrates an angioplasty catheter 20 having an angioplasty balloon 18 and a slidable sheath 30 having an ultra-thin section 34, the sheath coaxially situated about the balloon angioplasty catheter 20 (see col. 3 lines 58-63 and col. 4 lines 17-18 and 36-

37). Nowhere within the Fischell patent does it teach that angioplasty balloon 18 comprises a port to a vessel as that term is understood by one with ordinary skill in the art and as claimed and described by the Applicant. Further, nowhere within the Fischell patent does it teach that angioplasty balloon 18 has a portion that “acts as an o-ring” as alleged by the Examiner. Furthermore, nowhere within the Fischell patent does it teach that a proximal portion of sleeve 34 is positioned proximal to a port vessel. More specifically, Fischell does not teach wherein the o-ring inner diameter is greater than the diameter of the stent deployment assembly and less than the diameter of the distal end of the sleeve, wherein the protective sleeve is sized to be removed from covering the stent framework upon contact of the distal end of the protective sleeve with a proximal side of the o-ring as the stent enters the vessel, as recited in amended claim 1.

Fischell teaches an ultra thin distal section for covering a stent reciting at col 4 lines 37-51:

[t]he ultra-thin distal section 34 is shrunk down onto the proximal elastomer band 14P, the stent 40, the distal elastomer band 14D and the proximal portion 15P of the gradually tapered distal tip 15. A securing tube 16 fixedly attached at its distal end to the distal tip 15 is shrunk tight down over the distal portion of the ultra-thin distal section 34 thereby securing it during delivery of the primary stenting system 10 into the human body. Although the securing tube 16 holds the ultra-thin distal section 34 against the distal tip 15, the ultra-thin distal section 34 can still be pulled proximally out from under the securing tube 16 so as to unsheath the stent 40. It should be noted that the distal tip 15 is molded so that there will be a continuous outer surface at the transition 8 from the distal tip 15 to the securing tube 16. (emphasis added)

At most Fischell teaches that the ultra thin distal section covers the stent during delivery to the treatment site. Fischell does not teach that the sleeve is removed as the stent enters the vessel. In fact nowhere within the Fischell patent does it teach or suggest these limitations. For at least these reasons, the Fischell patent does not anticipate claim 1 or any claim depending therefrom.

Claims 5, 7 and 8 depend from claim 1 and include all of the limitations of that claim. Thus for at least this reason, claims 5, 7 and 8 are not anticipated by the Fischell patent. For these reasons, the withdrawal of the rejection of claims 1, 5, 7 and 8 under 35 U.S.C. § 102(b) is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

B. Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Fischell patent

The Applicant traverses this rejection. The Applicant respectfully asserts that the Fischell patent fails to disclose, teach, or suggest all the claim limitations of dependent claim 6.

As noted above, the Fischell patent does not teach or suggest all of the claim limitations of claim 1. Specifically, the Fischell patent does not teach or suggest, at least, the port including an o-ring having an o-ring inner diameter, the o-ring disposed at a distal end of the port wherein a proximal portion of the sleeve is positioned proximal to the o-ring and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1.

Claim 6 depends from independent claim 1 and includes all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that dependent claim 6 is allowable over the Fischell patent for at least the same reasons as set forth above with respect to independent claim 1.

The withdrawal of the rejection of claim 6 as being unpatentable over the Fischell patent is respectfully requested.

C. Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell in view of Roberts

This rejection is traversed. As noted above in section A, the Fischell patent does not teach or suggest all of the claim limitations of claim 1. Specifically, the Fischell patent does not teach or suggest, at least, the port including an o-ring having an o-ring inner diameter, the o-ring disposed at a distal end of the port wherein a proximal portion of the sleeve is positioned proximal to the o-ring and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1. The Roberts patent does not cure this defect. At

most, the Roberts patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve. Thus, Fischell in view of Roberts does not teach or suggest all of the claim limitations of independent claim 1.

Claim 9 depends from independent claim 1 and includes all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that dependent claim 9 is allowable over Fischell in view of Roberts for at least the same reasons as set forth above with respect to independent claim 1. The withdrawal of the rejection of claim 9 as being unpatentable over Fischell in view of Roberts is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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